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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,421	01/22/2001	Michael J. Shamblott	JHU1750-1	9551

7590

09/11/2006

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EXAMINER

CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/767,421

Applicant(s)

SHAMBLOTT ET AL.

Examiner

Deborah Crouch, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-13,15,16 and 22-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9-13,15,16 and 22-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

Applicant's arguments filed June 12, 2006 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1, 9-13, 15, 16 and 22-32 are pending.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 9-13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,453,357 issued September 26, 1995 (Hogan) in view of Shablott et al (1998) *Proced. Natl. Acad. Sci.* 95, pp. 13726-13731 (ref. AE).

Hogan teaches mouse embryoid body cells isolated from mouse embryoid bodies (EB's), rounded colonies of densely packed ES-like cells, produced by the culture of mouse primordial germ cells (col. 6, lines 19-49). Hogan describes the picking of single clones of EB-derived mouse cells, indicating clonal selection from a single EB-derived cell (col. 8, lines 5-9). Hogan offers motivation in stating ES cells from other mammals, such as humans, can be produced using the methods described therein for mouse (col. 5, lines 3-5 and col. 9, lines 18-11). Hogan offers additional motivation in stating derivatives of human ES cells, produced by the method disclosed therein, could treat neurodegenerative disease (col. 5, lines 32-34). Hogan also teaches the mouse EBD-cells to undergo at least 20 population doublings (col. 8, lines 14-16). Hogan further teaches that LIF may not be required for the maintenance of ES cells, which are interpreted to be the cells of the claims (col. 4, lines 55-67).

Art Unit: 1632

Shamblott teaches embryoid bodies (EB's) produced from human primordial germ cells (hPGC's) (13729, col. 1, parag. 1-12). Shamblott offers motivation in stating the human pluripotent stem cells produced therein would provide for studies of human embryogenesis, transplantation therapies, and defining culture conditions and differential gene expression for cell-type differentiation (page 13730, col. 1, parag. 2, lines 1-8).

As the presently claimed cells are derived from human primordial germ cells, the ordinary artisan at the time of filing would have reasonably expected the physiological characteristics to be the same for the claimed cells and those of Hogan even given species differences. Thus, the cells of Hogan in view of Shamblott undergo at least 30 or at least 60 population doublings, proliferate under conditions nonpermissive for the proliferation of human EG cells, proliferate under culture conditions lacking LIF, a fibroblast feeder layer, or both, and transfectable with a retrovirus, lentivirus or both. There is no evidence to the contrary on the record. Products obvious over those in the art would be expected to have the same properties absent evidence to the contrary.

Therefore at the time of the present invention, it would have been obvious to produce human EBD-cells in view of the production of mouse EBD-cells as taught by Hogan in view of Shamblott teachings human EB's. The prior art offers the requisite teachings, suggestions and motivation to combine, and a reasonable expectation of success.

Claims 22-24, 27 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,453,357 issued September 26, 1995 (Hogan) in view of Shamblott et al (1998) *Proced. Natl. Acad. Sci.* 95, pp. 13726-13731 (ref. AE).

Hogan teaches a method of producing EBD-cells comprising culturing primordial germ cells to form an embryoid body), rounded colonies of densely packed ES-like cells, digesting the embryoid body with trypsin to provide EBD-cells and culturing the EBD-cells in media comprising h bfgf2 (col. 6, lines 20-48). Hogan describes the picking of single clones

Art Unit: 1632

of EB-derived mouse cells, indicating clonal selection from a single EB-derived cell (col. 8, lines 5-9). Hogan also teaches the mouse EBD-cells to undergo at least 20 population doublings, which encompasses 30 population doublings (col. 8, lines 14-16). Hogan further teaches that LIF may not be required for the maintenance of ES cells, which are interpreted to be the cells of the claims (col. 4, lines 55-67). LIF is required for the growth of EG cells as stated in the specification (specification, page 8m lines 2-3). Hogan teaches culture of EBD-cells on feeder cells, which is a matrix. Hogan offers motivation in stating ES cells from other mammals, such as humans, can be produced using the methods described therein for mouse (col. 5, lines 3-5 and col. 9, lines 18-11). Hogan offers additional motivation in stating derivatives of human ES cells, produced by the method disclosed therein, could treat neurodegenerative disease (col. 5, lines 32-34).

Shamblott teaches embryoid bodies (EB's) produced from human primordial germ cells (hPGC's) (13729, col. 1, parag. 1-12). Shamblott offers motivation in stating the human pluripotent stem cells produced therein would provide for studies of human embryogenesis, transplantation therapies, and defining culture conditions and differential gene expression for cell-type differentiation (page 13730, col. 1, parag. 2, lines 1-8).

Thus, at the time of filing, it would have been obvious to the ordinary artisan to follow the method of Hogan to produce human EBD cells given the method of producing human EB's from hPGC culture as taught by Shamblott given the teachings and motivations provided. The cited prior art provides the requisite teaching, suggestion and motivation, as well as a reasonable expectation of success.

Claims 22 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,453,357 issued September 26, 1995 (Hogan) in view of Shamblott et al (1998) *Proced. Natl. Acad. Sci.* 95, pp. 13726-13731 (ref. AE) further in view of Rohwedel et al (1996) *Cell Biol. Internat.* 20, pp. 579-587 (ref. AC).

Art Unit: 1632

Hogan teaches a method of producing EBD-cells comprising culturing primordial germ cells to form an embryoid body), rounded colonies of densely packed ES-like cells, digesting the embryoid body with trypsin to provide EBD-cells and culturing the EBD-cells in media comprising h bfgf2 (col. 6, lines 20-48). Hogan offers motivation in stating ES cells from other mammals, such as humans, can be produced using the methods described therein for mouse (col. 5, lines 3-5 and col. 9, lines 18-11). Hogan offers additional motivation in stating derivatives of human ES cells, produced by the method disclosed therein, could treat neurodegenerative disease (col. 5, lines 32-34).

Shamblott teaches embryoid bodies (EB's) produced from human primordial germ cells (hPGC's) (13729, col. 1, parag. 1-12). Shamblott offers motivation in stating the human pluripotent stem cells produced therein would provide for studies of human embryogenesis, transplantation therapies, and defining culture conditions and differential gene expression for cell-type differentiation (page 13730, col. 1, parag. 2, lines 1-8).

Rohwedel teaches the culture of mouse EB cells on tissue culture plates coated with gelatin for morphological studies (page 580, col. 2, parag. 1, lines 14-18). Morphological studies are a part of a study of embryogenesis. It is noted that gelatin is a hydroxylation product of collagen I.

Thus, at the time of filing, it would have been obvious to the ordinary artisan to follow the method of Hogan to produce human EBD cells given the method of producing human EB's from hPGC culture as taught by Shamblott, culturing the EBD cells on collagen I coated plates given the teachings and motivations provided. The cited prior art provides the requisite teaching, suggestion and motivation, as well as a reasonable expectation of success.

Art Unit: 1632

Claims 25 and 26 are free of the prior art. At the time of filing the prior art did not teach or suggest methods of obtaining a human EBD cell comprising culturing resulting EBD cells in the particular media claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

September 2, 2006